FDA and the Reuse of Single Use Devices: Policy Now Established

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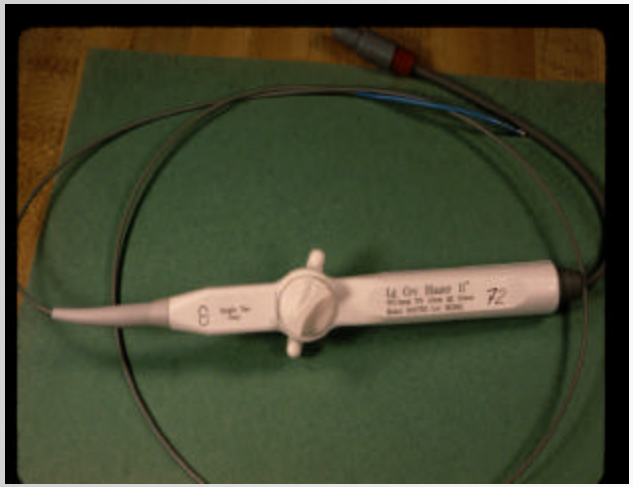
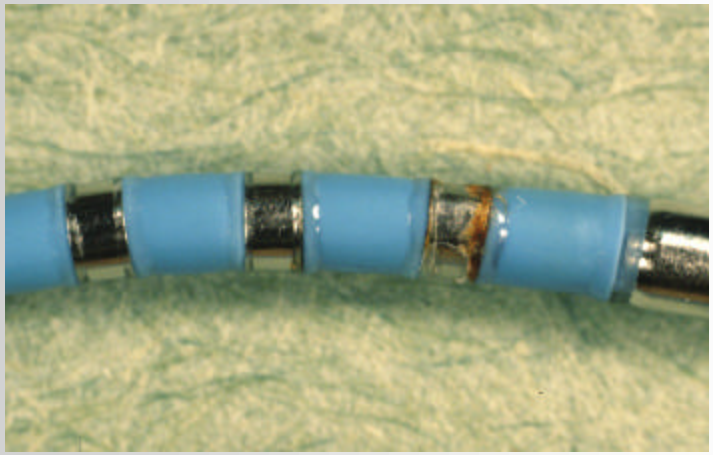
Objectives of Presentation

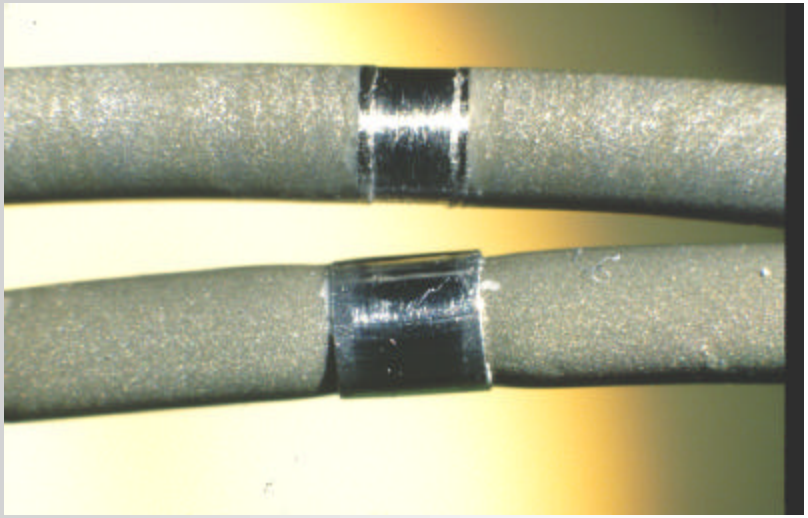
- Explain how we arrived at this issue
- Describe FDA's now "finalized" regulatory strategy
- Describe efforts still ongoing at the FDA to resolve the reuse area

Why Deal with this Issue

- Identical regulatory controls
  - ***Reprocessing IS manufacturing***
- Public concern
- FDA research shows reprocessing may be feasible, but is difficult and possibly ***dangerous***
  - Minimal evidence of problems does not mean the current practice is safe and effective

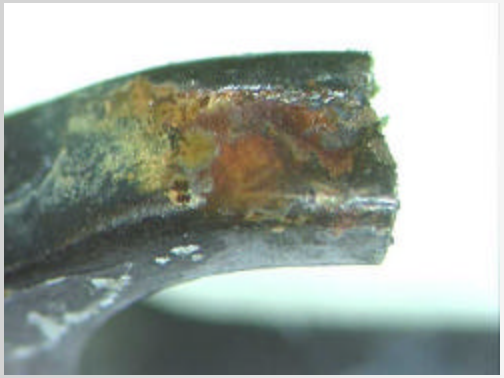
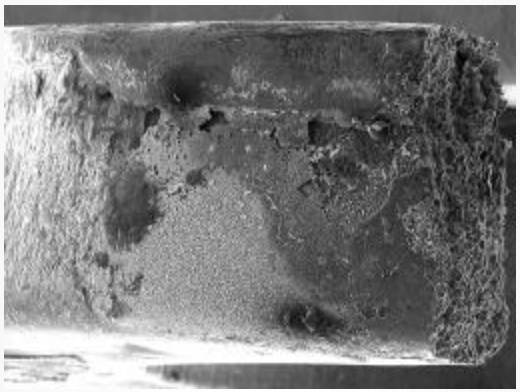
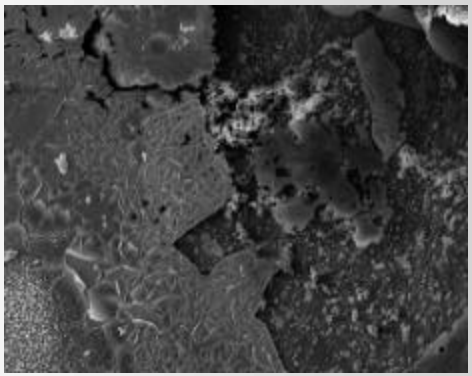






Validation of Materials

- Metal used for SUD jaws: Modification of the heat treatment process made device more robust for the first use but caused cracking when reprocessed due to *stress corrosion cracking and hydrogen embrittlement*

⇨ Refurbishers have to understand materials and manufacturing process

Design, Validation & QS

- SUD’s are validated and designed for one use
  - Materials are chosen to ensure maximum performance for the intended single use
  - Biocompatibility is ensured for materials exposed to the intended environment
  - Many devices are subjected to miniaturisation to further reduce unnecessary trauma of the patient and enhance functionality to improve procedures
  - OEM`s validation and performance testing is limited to initial failure

EP Catheter Incident

Product: EP catheter with tip electrode and several ring electrodes used for diagnostic and ablation

Reprocessed 3 times by 3´rd party reprocessing firm in Germany, although evidence of the failure mode was available

Electrodes separated - moved distally - heart valve trapped between both Electrodes. Catheter had to be pulled back by using extensive force which damaged the heart valve.
Liability currently discussed: Manufacturer - User - Refurbisher?

EP Catheters

- Comparison of new and reprocessed catheter tips
- Implantation into the jugular veins of dogs
  standard in vivo thrombogenicity tests
- Result of NAMSA analysis
  - New catheter, 4 hours: minimal thrombosis
  - Refurbished catheter, 2 hours: slight to moderate thrombosis

⇨ Reprocessed devices which are not adequately cleaned pose a measurable higher risk to patients

Areas of Laboratory Evaluation

- **Cleaning of devices**
- **Device functionality after reprocessing**
- **Material changes due to reprocessing**
- **Standards Development at AAMI**
  - "Sterilization of medical devices - Requirements for products labeled 'Sterile'" is being revised. Should be final soon
  - "Bacterial Endotoxin - Test Methodologies …" is out for comment
  - New standard on "Cleaning of Medical Devices" - Working group is meeting 11/15

Current Guidance and Plans

- Guidance issued August 14, 2000
- Third party reprocessors: remain under all non-premarket provisions of FD&C Act
- Hospitals: Have one year from final date of guidance for non-premarket compliance
  - Hospital inspections via JCAHO?
- Premarket submissions will begin in Feb. 2001

Premarket Submissions by Risk

Device Class	Submission Date
Class III	February, 2001
Class II	August, 2001
Class I	February, 2002

Issues Still in Development

- Guidance for premarket submissions
- Guidance for GMP/QSR inspection
- “High-risk” exempt products: should they maintain their exemption
- Open but unused devices
- Labeling issues
  - For the reprocessed product
  - For the original equipment manufacturer (OEM)
- Health care facilities other than hospitals

General Approach to Premarket Review

- We are evaluating a new device, not a process for 510(k)s and PMAs
- Apply the same procedures and guidance as for any other new device in least burdensome manner
- New device single use or reusable
- Reuse not a new intended use

Some Technical Concerns

- Control of “raw material”
- Defining the specifications
- Identification of changes to OEM device
- Cleaning and sterilization procedures
- Functionality of a reprocessed device
- Bundling of submissions
- Labeling

Inspection Authority & Focus

- Authority: Section 704 of the Federal Food, Drug and Cosmetic (FD&C) Act
- Primary Focus: Quality System Regulation,

  21 CFR Part 820
- Other Areas of Focus:
  - Medical Device Reporting, 21 CFR Part 803
  - Corrections and Removals, 21 CFR Part 806
  - Tracking, 21 CFR Part 821
  - Labeling, 21 CFR Part 801
  - Premarket Requirements, 21 CFR 807 and 814

Who Will Conduct Inspections?

- FDA for Third-Party Reprocessors
- Possibly JCAHO and Some State Survey Agencies for Hospital Reprocessors
- However, JCAHO is Hesitant and Some States May Not Have Interest/Expertise to Conduct Reuse Audits
- FDA Will Inspect Hospital Reprocessors to Document Enforcement Actions or, at Other Times, if Needed

Key Elements of Quality System Regulation

- Management Controls
- Design Controls
- Corrective and Preventive Actions
- Production and Process Controls

Where Do We Go From Here?

- Non-Premarket Requirements in Effect Now for Third Parties and in One Year for Hospitals
- Developing Inspection Guidance
- Developed a Plan to Inspect All Third-Party Reprocessors in FY 20001

Where Do We Go From Here?

- Working on JCAHO Contract to Audit Hospitals
- Early Inspections/Audits of Hospitals Will be Focused on Education - Not Enforcement
- Inspection Emphasis on SUDs Representing Greater Risk After Reprocessing

Vision for the Future

Current Reality

- Widespread practice with little data on safety or effectiveness
- Single use labels not clearly meaningful; don't identify vulnerabilities
- Patients are not informed - experimentation?

Future Vision

- FDA approach will be risk and science based
- Premarket submissions will be required beginning February 2001
- Horizontal and vertical standards could be useful
- Substantial outreach
- Leverage outside parties, e.g., JCAHO